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10/511,282	04/08/2005	Katariina Maria Hutterer	PB0217	1837

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Amersham Biosciences Corp
Patent Department
800 Centennial Avenue
Piscataway, NJ 08855

EXAMINER

DIETERLE, JENNIFER M

ART UNIT	PAPER NUMBER
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4111

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02/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,282

Applicant(s)

HUTTERER ET AL.

Examiner

Jennifer Dieterle

Art Unit

4111

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 12, 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-824)
- Paper No(s)/Mail Date 1/8/09, 4/30/07, 10/12/04
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a multiplexed capillary electrophoresis system, classified in class 204, subclass 451.
- II. Claims 14-22, drawn to a method for separating and detecting components in a complex biological sample, classified in class 204, subclass 450.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, for example, the process as claimed in invention II can be practiced by ion exchange chromatography.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Yonggang Ji on January 29, 2009 a provisional election was made without traverse to prosecute the invention of II, claims 14-22. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 1-13 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 7 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

Claim Objections

Claim 18 is objected to because of the following informalities: The abbreviations "HPLC" and "FPLC" are not defined in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 18, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Issaq et al. ("Multidimensional high performance liquid chromatography-capillary electrophoresis separation of a protein digest: An update", 2001) with evidence from Nelson et al. (U.S. Pat. No. 6,074,827).

Regarding claims 14 and 18, Issaq et al. teach a separation and detection technique utilizing high performance liquid chromatography (hereinafter "HPLC") and parallel gel capillary electrophoresis (abstract). Issaq et al. teach the process of first injecting the digest (sample) into the HPLC instrument and collecting the fractions. The collected fractions were analyzed by UV-absorption and the samples were derivatized with fluorescein isothiocyanate prior to capillary electrophoresis (hereinafter "CE") (page 1133).

With regard to part (c) of claim 14, the first separation and detection means by chromatography is based on a different property than CE. For example, Nelson et al. teach that in conventional affinity separation a ligand is attached directly to a stationary solid support and captures and/or separates the target substance based on its affinity for the ligand (col. 19, lines 66-67, col. 20 lines 1-3) and that CE is the process by which particular entities or species are moved through a medium in an electrophoretic

chamber of capillary dimensions under the influence of an applied electric field (col. 1, lines 20-23).

Regarding claims 19 and 22, Issaq et al. teach the use of high performance parallel gel CE as the second separation and detection means. Issaq et al. use a 96 well microtiter plate in which the capillaries are set-up side by side (page 1133, column 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being obvious over Issaq et al.

Regarding claims 15-17, Issaq et al. teach that an allura red dye is added to each of the wells prior to CE in order to create a fluorescence spectra (page 1134, bottom of the first column). While the first phase of separation involving HPLC in Issaq et al. use UV absorption to analyze the sample, it could employ a dye and detect the separation based on fluorescence as it does with the CE step. Substituting a dye detection method for UV absorption will not yield different results. The sample will still undergo separation and the separation can be detected. Although Issaq et al. do not disclose using a dye to detect separation based on HPLC, the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *See In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), *See also* MPEP 2144.04(VI)(B).

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Issaq et al. in further view of Kozulic (U.S. Pat. No. 5,840,877).

Regarding claims 20 and 21, Issaq et al. teach a two phase separation of a biological sample using CE as the second method of separation, however, Issaq et al. do not teach the use of galactomannan or dextran as a sieving matrix in the CE separation.

Kozulic teaches the use of galactomannan and dextran as sieving matrices in CE separation (abstract and col. 14, lines 7-11).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, A.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Issaq et al. by using a galactomannans or dextran as a sieving matrix as taught by Kozulic, because Kozulic teaches a sieving matrix which provides enhanced selectivity (col. 14, lines 18-19).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on (571) 272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Harry D Wilkins, III/
Primary Examiner, Art Unit 1795

JMD